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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MARX, IRENE

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



### **DETAILED ACTION**

The application should be reviewed for errors.

To facilitate processing of papers at the U.S. Patent and Trademark Office, it is recommended that the Application Serial Number be inserted on every page of claims and/or of amendments filed.

Applicant's election without traverse electing to prosecute the invention of Group I, claims 1-2 on 7/18/06 is acknowledged.

Claims 1-2 are being considered on the merits. Claims 3-18 are withdrawn from consideration as directed to a non-elected invention.

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 2 are rejected under 35 U.S.C. 101 because this claim reads on the organism per se which is found in nature and thus, is unpatentable to applicant. Consequently, the claim does not embody patentable subject matter as defined in 35 USC 101. See, e.g., *American Wood v. Fiber Disintegrating Co.*, 90 U.S. 566 (1974); *American Fruit Growers v. Brogdex Co.*, 283 U.S. 1 (1931); *Funk Brothers Seed. Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948); *Diamond v. Chakrabarty*, 206 U.S.P.Q. 193 (1980).

It is suggested that applicant use the language "a biologically pure culture" in connection with the strain to identify a product that is not found in nature and to indicate the hand of man.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1651

Claim 2 is vague and indefinite in the use of parenthesis, since it is unclear whether the parenthetical material is or is not intended to be part of the claim. In addition, the designation LFF1 in this context does not clearly define a strain. The phrase “a strain of the same genus as the LFF1 strain is redundant, since the strain belongs to the genus *Thraustochytrium*.

Claim 2 is further vague and indefinite in the recitation of “a strain having fungological properties substantially identical to those of the LFF1 strain”. It is unclear which properties are “fungological” or how similar the strain as claimed is intended to be as encompassed by “substantially identical”. It is suggested that the language -- a strain having all of the identifying characteristics of the strain FERM BP-08568-- be substituted therefor.

### ***Claim Rejections - 35 USC § 112***

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ a novel strain of *Thraustochytrium* to obtain a specific product. The written description of that strain and the method of isolating is insufficiently reproducible. Therefore, a deposit for patent purposes is required. The specification discloses at page 7 that *Thraustochytrium* LFF1 strain was deposited at National Institute of Advanced Industrial Science and Technology under Budapest Treaty conditions on December 10, 2003.

For compliance with the rule, it must be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent. MPEP 2403.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1651

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Singh *et al.* (1996) or Singh *et al.*, or Li *et al.* or Lewis *et al.* or Iida *et al.* or Bajpai *et al.* (1991) or Bajpai (2000).

The claims are directed to a *Thraustochytrium* capable of producing docosahexaenoic or a specific strain LFF1 or a strain having fungological properties substantially identical to those of the LFF1 strain”.

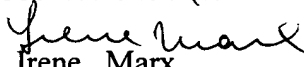
Each of Singh *et al.* (1996) or Singh *et al.*, or Li *et al.* or Lewis *et al.* or Iida *et al.* or Bajpai *et al.* (1991) or Bajpai (2000) discloses a *Thraustochytrium* strain that is capable of producing docosahexaenoic and which at least has fungological properties substantially identical to those of the LFF1 strain if it is not substantially identical to strain LFF1. See, e.g., respective abstracts or Lewis *et al.* Table 1.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Irene Marx  
Primary Examiner  
Art Unit 1651